NOV 2 8 2000

Safety and Effectiveness Summary

K002714

1. Submitter's Name, Address and Contact Person

Submitter

Wartner Medical Products
Beneluxweg 37
4904 SJ Oosterhout
Netherlands

Telephone: 00 31 162 472 489
Facsimile: 00 31 162 472 487

Contact Person

Judy Magner
N. Wilson Consulting Inc.
25 Bellini Ave.
Brampton, Ontario
L6T 3Z8 CANADA

Telephone: 905-794-3339
Facsimile: 905-794-0633

Date Summary Prepared: August 6, 2000

2. Name of Device

Wartner Wart Removal System

3. Name of Predicate Device(s)

Histofreezer Cryosurgical System, by STC Technologies, Inc.

4. Description of Device

Wartner Wart Removal System is a cryosurgical system for the treatment of warts. It consists of

- A canister filled with 35 ml of a liquid mixture of the compressed gases dimethyl ether and propane. This gas mixture does not harm the ozone layer, and has a four-year shelf life.
- Ten foam applicators
- An applicator stick/key for holding a foam applicator, required to dispense the liquid to the applicator, and held by the person during treatment
- An illustrated description of how to use the product

5. Statement of Intended Use

Wartner Wart Removal System is intended for the treatment of common warts.

Safety/Ease of Use:
Wartner's design incorporates the use of a safety valve that cannot be actuated unless the foam applicator and holder are in place. The Histofreezer valve does not incorporate this safety feature and is actuated until droplets are seen at the end of the foam applicator.

7. Conclusion

Based on the information presented above it is concluded that the proposed Wartner Wart Removal System is safe and effective for its intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2000

Wartner Medical Products
c/o Ms. Judy Magner
N. Wilson Consulting, Inc.
25 Bellini Avenue
Brampton, Ontario
L6T 3Z8 Canada

Re: K002714
Trade Name: Wartner Wart Removal System
Regulatory Class: II
Product Code: GEH
Dated: August 29, 2000
Received: August 31, 2000

Dear Ms. Magner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Wartner Medical Products
Wartner Wart Removal System

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K002714

Device Name: **Wartner Wart Removal System**

Indications for Use : **Wartner Wart Removal System is intended for the treatment of common warts.**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ____
(Optional Format 1-2-96)

002 for Mark N Milhenson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002714